

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
MICHAEL J. ATKINS
170 HARBOR WAY
PO BOX 511
SOUTH SAN FRANCISCO, CA 94083-0511

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference EX04-065C-PC		Date of mailing (day/month/year) 09 JUN 2005 FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US04/35469	International filing date (day/month/year) 22 October 2004 (22.10.2004)	Priority date (day/month/year) 24 October 2003 (24.10.2003)
International Patent Classification (IPC) or both national classification and IPC IPC(7): C07C 233/64; C07C 275/06, 275/28; A61K 31/16, 31/17 and US Cl: 564/47, 48, 155, 158; 514/596, 616		
Applicant EXELIXIS, INC.		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer SHAILENDRA -. KUMAR Telephone No. (571)272-1600
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Valeriu Bell-Horus
for

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/35469

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☐ paid additional fees
- ☐ paid additional fees under protest
- ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
- ☒ not complied with for the following reasons:
- See the lack of unity section of the International Search Report (Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-14(in part) and 23-31(in part)

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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims NONE YES

Claims 1-14(in part) and 23-31(in part) NO

Inventive step (IS)

Claims NONE YES

Claims 1-14(in part) and 23-31(in part) NO

Industrial applicability (IA)

Claims 1-14(in part) and 23-31(in part) YES

Claims NONE NO

2. Citations and explanations:

Claims 1-14(in part) and 23-31(in part) lack novelty under PCT Article 33(2) as being anticipated by Goldstein et al (US 2003/0191279) or Herzig et al (US 5,877,218).

Goldstein et al, claim 7, anticipate instant claimed compounds, composition and method of use, when in the instant claims B is NR4, R3 is NR5R5, X and Y are O. Likewise, Herzig et al, column 19 and 20, various compounds, anticipate instant claimed compounds, composition and method treatment.

Claims 1-14(in part) and 23-31 lack an inventive step under PCT Article 33(3) as being obvious over Goldstein et al or Herzig et al. Goldstein et al, claim 7 or Herzig et al, various compounds in column 19-20, teach structurally similar compounds, composition and method of treatment as claimed herein. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to obtain compounds within the generic disclosure of the references, because they are structurally so similar, with the reasonable expectation of achieving a successful pharmaceutical composition for treating various diseases, absent evidence to the contrary.

Claims 1-14(in part) and 23-31(in part) meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.